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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,893	07/22/2002	David M Stern	59472-A-PCT-US/JPW/FHB	2372

7590 11/09/2005

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New York, NY 10036

EXAMINER	
EMCH, GREGORY S	
ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 11/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,893	STERN ET AL.	
	Examiner	Art Unit	
	Gregory S. Emch	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *42-69* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

Claims 1-41 were canceled and new claims 42-69 were added in the communication dated October 3, 2005. Claims 42-69 are pending.

Election/Restrictions

In the amendment dated October 3, 2005, Applicant elected with traverse Group II, claims 31-33. Applicant asserted that new claims 42-69 are directed to the subject matter of Group II and requested that all of the new claims be examined together. Further, Applicant asserted that there would not be a serious burden on the Examiner if restriction were not required, because a search of the prior art relevant to the claims of Group II would provide the relevant art for Groups I and III-V (p.9, paragraph 2).

Applicant's arguments have been fully considered and are not found persuasive because Group I is drawn to a method of inhibiting the binding of a β-sheet fibril to RAGE on the surface of a cell, Group II is directed to a method for treating a patient, and Group III is drawn to a compound not previously known to inhibit binding of a β-sheet fibril to RAGE and an associated method of using and an associated method of making said compound, Group IV is drawn to an assay method which recites transfected cells, and Group V is drawn to a compound determined by the method of Group IV. All five Groups represent distinct and independent inventions the search and examination of which is not co-extensive and represents a search burden. Therefore, the lack of unity requirement set forth in the communication dated August 29, 2005 is

still deemed proper and is therefore made FINAL. Additionally, pending claims 42-69 are subject to a lack of unity requirement as set forth *infra*.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 42-45 and 55-69 are drawn to a method for preventing and/or treating a disease involving β-sheet fibril formation other than Alzheimer's disease in a subject, which comprises administering to the subject a binding-inhibiting amount of a compound capable of inhibiting binding of the β-sheet fibril to RAGE, wherein the compound is sRAGE or a fragment thereof.

Group II, claim(s) 42, 46, 53, and 55-69 are drawn to a method for preventing and/or treating a disease involving β-sheet fibril formation other than Alzheimer's disease in a subject, which comprises administering to the subject a binding-inhibiting amount of a compound capable of inhibiting binding of the β-sheet fibril to RAGE, wherein the compound comprises an antibody or portion thereof.

Group III, claim(s) 42, 47-52, and 55-69 are drawn to a method for preventing and/or treating a disease involving β-sheet fibril formation other than Alzheimer's disease in a subject, which comprises administering to the subject a binding-inhibiting amount of a

compound capable of inhibiting binding of the β-sheet fibril to RAGE, wherein the compound is an anti-RAGE antibody or a portion thereof.

Groups IV-VII, claim(s) 42, 54, and 55-69 are drawn to a method for preventing and/or treating a disease involving β-sheet fibril formation other than Alzheimer's disease in a subject, which comprises administering to the subject a binding-inhibiting amount of a compound capable of inhibiting binding of the β-sheet fibril to RAGE, wherein the compound comprises a peptide, a peptidomimetic, a nucleic acid, or an organic compound with a molecular weight less than 500 daltons.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Each of inventions I-VIII are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires administering sRAGE or a fragment thereof, which is not required by Inventions II-VII. Invention II requires administering an antibody or portion thereof, which is not required by Inventions I and IV-VII. Inventions II and III are drawn to administration of different antibodies, which have independent and distinct properties, and a search of either of the inventions would not necessarily reveal art to the other Invention. Invention III requires administering an anti-RAGE

antibody or portion thereof, which is not required by Inventions I and IV-VII. Invention IV requires administering a generic peptide, which is not required by Inventions I-III and V-VII. Invention V requires administering peptidomimetic, which is not required by Inventions I-IV, VI, and VII. Invention VI requires administering a nucleic acid, which is not required by Inventions I-V, and VII. Invention VII requires administering an organic compound with a molecular weight less than 500 daltons, which is not required by Inventions I-VI.

Therefore, a search and examination of both of these methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

This application contains claims directed to the following patentably distinct species of the claimed inventions II and III:

a. Human

b. Humanized

c. Chimeric

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 49 is generic.

If applicant selects either of Inventions II and III, one species from the anti-RAGE antibody or antibody group must be chosen to be fully responsive.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

This application contains claims directed to the following patentably distinct species of the claimed inventions I-VIII:

d. Amyloid fibril

e. Prion-derived fibril

f. Amyloid-β peptide

g. Amylin

h. Amyloid A

i. Prion-derived peptide

j. Transthyretin

k. Cystatin C

l. Gelsolin

m. Peptide capable of forming amyloid

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 55-57 are generic.

If applicant selects any one of Inventions I-VIII, one species from the β-sheet fibril group must be chosen to be fully responsive.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the

case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct species of the claimed inventions I-VIII:

n. Aβ (1-39)

o. Aβ (1-40)

p. Aβ (1-42)

q. Aβ (1-40) Dutch variant

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 58 is generic.

If applicant selects any one of invention I-VIII, one species from the amyloid-β peptide group must be chosen to be fully responsive.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

This application contains claims directed to the following patentably distinct species of the claimed inventions I-VIII:

r. Diabetes

s. Hyperlipidemic atherosclerosis

t. Neuropathy

u. Nephropathy

v. Amyloidosis

w. Wound associated with diabetes

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 64-69 are generic.

If applicant selects any one of invention I-VIII, one species from the disease group must be chosen to be fully responsive.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached on Monday through Friday from 8:30AM to 5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner
Art Unit 1649
November 7, 2005

JOSEPH MURPHY
PATENT EXAMINER